

APPENDIX H: COST MEMORANDA FOR DETERMINING EPA PER SUBMISSION REPORTING COSTS  
AND EPA'S REVIEW PROCESS

This appendix provides memoranda used to calculate the EPA costs. The six sections are:

- The Costs to EPA of Maintaining the BSAC;
- Overview of EPA's review process;
- Derivation of FTE Estimates for Calculating EPA Costs of the Rule;
- Revised estimates by the Exposure Evaluation Division for hours to review biotechnology submissions;
- Revised estimates by the Information Management Division for man hour estimates for various biotech submissions review;
- Revised division hour estimates per submission type.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEB 21 1990

OFFICE OF  
PESTICIDES AND TOXIC SUBST.

MEMORANDUM

SUBJECT: The Costs to EPA of Maintaining the BSAC

FROM: Donna Ozolins  
Regulatory Impacts Branch (TS-779)

TO: Charlene Dunn  
BSAC Coordinator  
Office of Toxic Substances (TS-788)

As you recall I spoke to you several months ago about the costs to EPA of operating the Biotechnology Science Advisory Committee. This memo is to confirm our conversations and my notes, so that I may accurately estimate the BSAC costs.

There are 11 members on the full committee which meets three times a year. Assuming each meeting lasts only one day the following costs were estimated. For each one day meeting the costs for the room are \$930, and the court reporter is \$1,000. Of the eleven members, you stated some are paid a consulting fee not exceeding \$270 per day, and that some are paid travel not exceeding \$350 per person. The total full committee per meeting cost is calculated below, given the number of members paid consulting fees and travel.

FULL	\$1,620 (6 paid consulting fee * \$270)
COMMITTEE	2,450 (7 paid travel expenses * \$350)
	<u>1,930</u> (meeting costs)
	\$6,000

The per meeting subcommittee costs were calculated in a similar manner. Subcommittees are composed of 6-9 members, with some being paid and some not. The totals and number paid consulting and or travel fees is given below.

SUBCOMMITTEES	\$ 810 (3 paid consulting fees * \$270)
6 MEMBERS	1,400 (4 paid travel expenses * \$350)
	<u>1,930</u> (meeting costs)
	\$4,140

SUBCOMMITTEES	\$1,620 (6 paid consulting fees * \$270)
9 MEMBERS	2,100 (6 paid travel expenses * \$350)
	<u>1,930</u> (meeting costs)
	\$5,650

If I have recorded anything incorrectly, please let me know. If I do not hear from you by February 23 I will assume that I numbers I have used accurately reflect our conversation. Please call me with any questions or comments, 475-7189.

cc: Carol Rawie  
Christine Augustyniak  
Robert E. Lee, II  
RIB Files 508/RIAPD

### EPA's Review Process

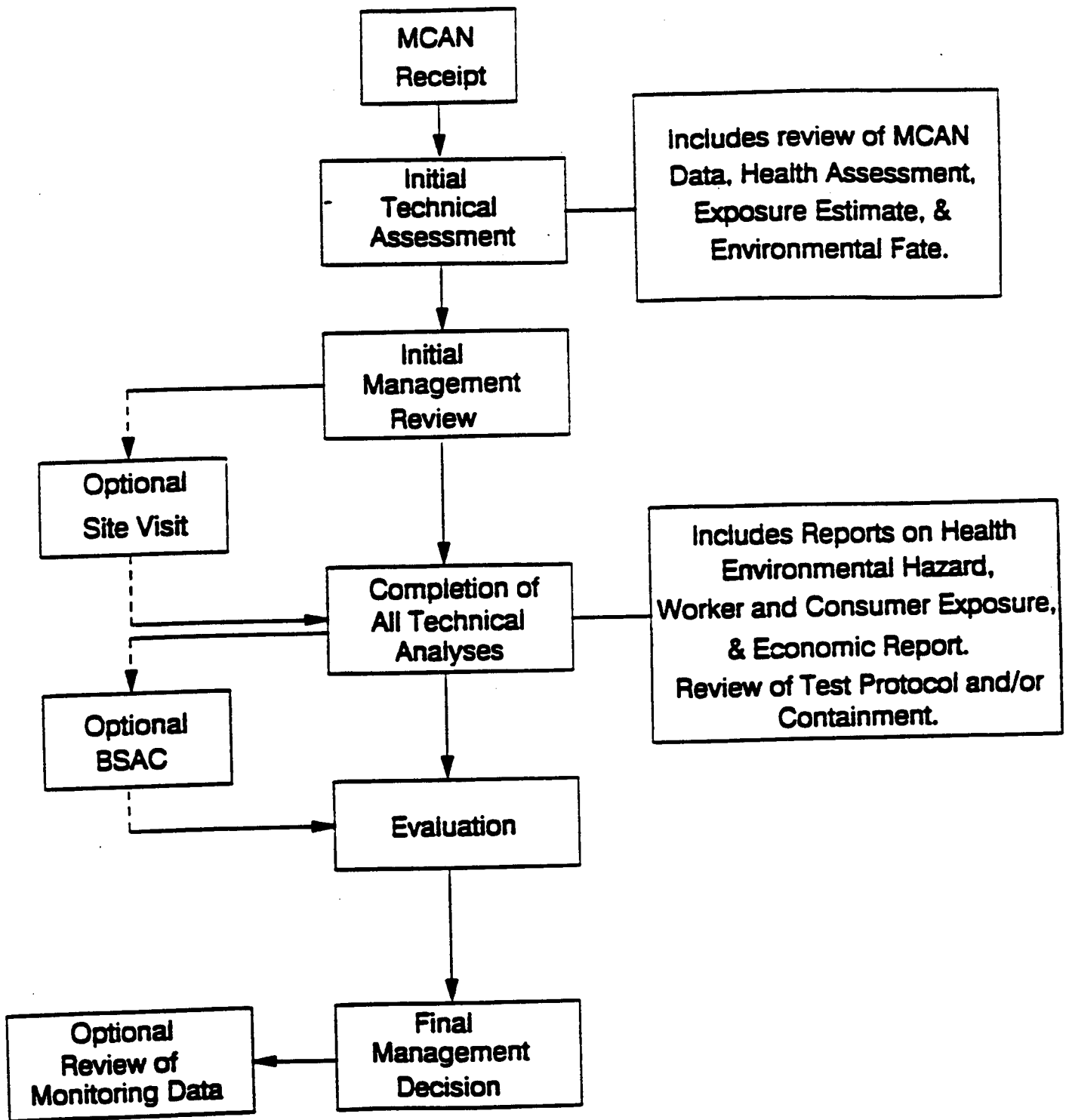
EPA's review process is based on the new chemicals program currently in place under Section 5 of TSCA. This analysis assumes that some elements of the review of microorganisms can be expected to take approximately the same time as comparable elements of the chemical review process.

It was more difficult to estimate the time requirements for other elements of the review for microorganism uses such as the development of monitoring protocol for releases by the environmental effects personnel. Aspects of the review that are extensions of what is currently done when reviewing chemical submissions include receiving submissions and placing them into review, and conducting a literature search.

For a MCAN and a TERA the reviews will be similar in many respects. However, TERA reviews are expected to be completed more rapidly. Figure H-1 depicts the stages of EPA's review process. In the initial technical assessment the submission receives a cursory check for completeness. Upon establishing that the submission is complete a literature search is performed for the microorganism. Any information pertaining to the microorganism and its use is collected. An initial review entails an assessment by a chemical engineer of the production process to determine the level of containment in place, and the potential for occupational or consumer exposure.

A health effects and fate review also is initiated immediately upon receipt of the submission. A toxicologist examines data on the microbial product for any potential harm to human health. Environmental scientists work with the release and site information provided by the engineer and in the submission to assess any detrimental effects to the environment for TERA submissions and MCANs. The initial review also serves to identify areas of uncertainty regarding the microorganism and any data deficiencies.

Figure H-1



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**EPA's Review Process**

The initial managerial review that follows the technical assessment provides the individual reviewers guidance across the technical aspects of the case. This initial review also establishes the level of effort that will be necessary to complete the review. For example, at this point EPA will decide if a site visit is necessary or if a BSAC subcommittee's assistance will be needed.

The individual assessors continue their reviews and complete their reports. An economic review begins that identifies benefits to the firm and society, projects the possible market that the microbial product will penetrate, and identifies substitutes for purpose of evaluating relative risk issues. The entire package is then integrated for final management review and approval. Approval can be granted outright or may be conditional upon EPA's receiving more data, and/or upon a legally binding agreement to undertake specific precautions or procedures.

The above described scheme will be the basic process for most of the submissions the Agency receives. Although the process is similar, there are differences in review time and emphasis for each submission type and microorganism class. The more familiar the Agency is with the microorganism and its use, the less review time needed. Finally, review time per case will differ based on whether or not an extensive environmental fate analysis must be performed. Review time also is likely to decrease, as the Agency gains experience and greater knowledge of microorganisms and their effects.

DIVISION HOUR ESTIMATES PER SUBMISSION TYPE  
YEAR 1

DIVISION	TERA		Released MCAN(altered)		Released MCAN(M/ TERA)		Contain MCAN		Portion o
	low	high	low	high	low	high	low	high	
HERD	384	478	108	126	108	126	283	283	16
EED	380	510	88	159	88	159	160	160	8
EID	160	170	85	109	85	109	88	88	22
CCD (pm)	300	500	300	500	250	400	283	400	160
CCD (ee)	150	250	150	250	125	200	142	200	0
IMD	105	110	43	53	43	53	108	108	0
OGC	8	16	8	16	4	4	3	3	11
Overhead	149	203	78	121	70	105	107	124	
TOTAL MD	1,636	2,237	860	1,334	773	1,156	1,173	1,366	217
TOTAL FT	0.79	1.08	0.41	0.64	0.37	0.56	0.56	0.66	0.10

Category 1 assumes all TERAs will involve a post-data review.

DIVISION HOUR ESTIMATES PER SUBMISSION TYPE

YEAR 5

DIVISION	Category 1		Category 2		Category 3		Category 4		5(e)
	low	high	low	high	low	high	low	high	
HERD	288	359	81	95	81	95	212	212	12
EED	285	383	66	119	66	119	120	120	6
E10	120	128	64	82	64	82	66	66	17
CCD (pm)	225	375	225	375	188	300	212	300	120
CCD (ea)	113	188	113	188	94	150	106	150	0
IMO	79	83	32	40	32	40	81	81	0
OGC	6	12	6	12	3	3	2	2	8
Overhead	112	153	59	91	53	79	80	93	
TOTAL NO	1,227	1,678	645	1,001	580	867	880	1,025	163
TOTAL F1	0.59	0.81	0.31	0.48	0.28	0.42	0.42	0.49	0.08

pm = Program Manager  
sq = Science Advisor



**MEMORANDUM**

June 13, 1991

**SUBJECT:** Estimate of hours to review biotechnology submissions

**FROM:** Gerald LaVeck, Microbiologist *GL*  
Exposure Evaluation Division

**TO:** Christine Augustyniak  
Regulatory Impacts Branch

I have completed my estimates of the time required for various biotech review activities as you requested in your memo. I changed the reporting from the forms that you sent, mostly because they didn't always capture all the resources that are required for a review. The closed system and environmental release MCAN estimates are based on previous experience and are probably fairly accurate. Since we haven't performed any of these yet, the TERA and Tier II estimates are guesses. The TME is based on the one case this division has done, so its accuracy is limited.

**Estimated hours for Biotechnology Submissions**

Description	Hours to complete		Extramural
	Environmental	Closed	
	Release	System	
<b>Bona Fide Submissions</b>			
HERD/EED/ETD: Assessment support	16.0	16.0	
<b>Prenotice Consultations</b>			
HERD/EED/ETD/IMD: Attendance at mtgs & meeting prep.	2.0	2.0	
<b>Exposure/Fate</b>			
EED: case review	8.0	8.0	
<b>CBI Assessment</b>			
All Divisions: Assessment	2.0	2.0	
<b>Focus</b>			
All Divisions: Focus attendance	2.0	2.0	
<b>Review Functions</b>			
Assessment			
EED: PMN customized statistics/searches			\$1,250.00
EED: PMN exposure modeling	8.0	8.0	
EED: Site Visit	24.0	0.0	
EED: PMN Review	150.0	120.0	
<b>Data and Protocol Review</b>			
EED: Fate test data review	8.0		
EED/HERD: Assess protocols	20.0		
<b>Dispositions</b>			
EED: EED Dispo	3.0	3.0	
EED: CCD Dispo attendance	1.0	1.0	
<b>Outside Review</b>			
All Divisions review briefing materials and attend meetings	2.0	2.0	
<b>Order Development/Negotiation/Review</b>			
All divisions: 1) Review of 5(e) orders, 2) Company meetings	8.0	8.0	
<b>Post Order Data Review</b>			
All Divisions: Post-order data review	80.0		
<b>Order Modifications</b>			
All divisions: 1) Review of data & arguments, 2) Company Meetings	8.0		
<b>Freedom of Information Act Requests</b>			
CCD: Response writing			
IMD: Response writing			
All Divisions: Response development	4.0		

**Estimated hours for Biotechnology Submissions**

<b>CBI Substantiation</b>			
<b>All divisions: performs CBI substantiation analyses</b>	<b>1.0</b>	<b>3.0</b>	
<b>IMD: Coordinate substantiation analysis</b>			
<b>Totals</b>			
<b>MCAN analysis, environmental release, site visit</b>	<b>231.0</b>		<b>\$1,250.00</b>
<b>MCAN analysis, environmental release, no site visit</b>	<b>207.0</b>		<b>\$1,250.00</b>
<b>Post MCAN data review</b>	<b>100.0</b>		
<b>MCAN analysis, closed system</b>	<b>159.0</b>		
<b>Bona Fides</b>	<b>16.0</b>		
<b>TERA, first time (80% of PMN time)</b>	<b>184.8</b>		<b>\$1,250.00</b>
<b>TERA, follow on (80% of first TERA)</b>	<b>147.8</b>		
<b>Tier II review</b>	<b>160.0</b>		
<b>Test Market exemption</b>	<b>200.0</b>		



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OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

June 10, 1991

NOTE

TO: Christine Augustyniak, ETD  
FROM: DeLois Powell, IMD *Dmp*  
Re: IMD Man Hour Estimates for Various Biotech Submissions  
Review

This presentation represents results of assessments by individual Sections within IMD. Specific types of submissions, including the bona fide submissions are identified. Values range from low - high.

CSS anticipates no more than one (1) hour per submission for each of two functions: 1) processing retrieval requests and 2) maintenance of database of information.

If we can be of further assistance, please give me a call at 245-4200.

cc: Henry Lau  
Y'Vonne Jones Brown  
Scott Sherlock  
Yvonne Kinney  
Juanita Geer  
Loren Zelsman  
Jerry Brown  
Frank Caesar

CIS

SUBMISSION TYPE

TERA (first time)

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	32-48
standard/detailed	10-16
control actions (TERA agreement)	04-06

TERA (follow-on)

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	10-16
standard/detailed	02-04
control actions (TERA agreement)	02-04

TERA Exemption

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	03-06
standard/detailed	00-00
control actions (Certification)	00-00

**CIS****MCAN**

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	25-60
standard/detailed	10-20
control actions (5(e) order)	05-10

**LCUE (Tier I)**

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	03-06
standard/detailed	00-00
control actions (Certification stmt.)	00-00

**LCU (TIER II)**

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	24-32
standard/detailed	16-16
control actions (Tier II exemption request approval)	08-10

CIS

**Bona Fide Submission Type**

<u>activity</u>	<u>simple</u>	<u>non precedent</u>	<u>precedent setting</u>
staff review	24-32	32-48	40-48
Workgroup review	00-00	05-10	08-16
Management review	01-02	05-10	10-20

**PDB/Dockets**

**SUBMISSION TYPE**

**TERA (first time)**

**TERA (follow-on)**

<b><u>activity</u></b>	<b><u>number of hours</u></b>
document receipt and tracking	05-10
FR notice prep.	00-00
docket prep/indexing	08-10
public access/FOIA response	03-05
document archiving	00-00
pre-focus	00-00
standard/detailed	00-00
control actions (TERA agreement)	00-00



**PDB/dockets****MCAN**

<u>activity</u>	<u>number of hours</u>
document receipt and tracking	05-10
FR notice prep.	05-10
docket prep/indexing	05-10
public access/FOIA response	06-12
document archiving	04-08
pre-focus	00-00
standard/detailed	00-00
control actions (5(e) consent order)	00-00

**LCUE (Tier I)**

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	00-00
standard/detailed	00-00
control actions (Certification stmt.)	00-00
docket prep/indexing	02-05

**PDB/Dockets****LCU (TIER II)**

<u>activity</u>	<u>number of hours</u>
pre-screen	00-00
pre-focus	00-00
standard/detailed	00-00
control actions (Tier II exemption request approval)	00-00
FR notice prep.	02-05
docket prep/indexing	02-05

DCO

SUBMISSION TYPE

TERA (first time)

<u>activity</u>	<u>number of hours</u>
initial submission	01-04
follow-up documents	01-02
archive	00-01

MCAN

<u>activity</u>	<u>number of hours</u>
pre-communication	00-01
initial submission	01-04
follow-up documents	01-03
notice of commencement	01-02
archive	01-02

TME

<u>activity</u>	<u>number of hours</u>
precommunication	00-01
initial submission	01-04
follow-up documents	01-02
archive	01-03

Revised Division Hour Estimates Per Submission Type

Year/Division	TERA hours		MCAN hours	
	low	high	low	high
Year 1				
HERD	384	478	108	283
EED <sup>a</sup>	185	185	207	159
ETD	160	170	85	88
CCD (pm)	300	500	250	400
CCD (sa)	150	250	125	200
IMD	64	102	69	152
OGC	8	16	4	3
Total hours	1251	1701	848	1285
FTE	0.60	0.82	0.41	0.62
Year 5 <sup>b</sup>				
Total hours <sup>a</sup>	938	1276	636	964
FTE	0.45	0.61	0.31	0.46

<sup>a</sup> The addition of extramural costs of \$1,250 for Year 1 and \$938 for Year 5 is shown in Table V-3.

<sup>b</sup> It is assumed that the review time for Year 5 submissions represents a 25 percent decrease from review time for Year 1 submissions.